REMARKS

1. Status of the Claims

It is noted with appreciation that the Examiner has withdrawn the initial restriction requirement. As discussed below, original claims 1-14 have been canceled, and replaced with new claims 15-21. While the new claims have been submitted in order to expedite prosecution in this application, this action is taken without prejudice to Applicant's right to pursue other disclosed subject matter in any desired divisional/continuation applications.

2. Sequence Compliance

Submitted with this response is a suitable Sequence Listing in electronic form to be used as the electronic and paper copy. In addition, the Specification has been amended to include the appropriate SEQ ID. NOs. on page 32.

3. Claim Rejections – 35 USC § 112 (Written Description)

Claims 1-5 and 8-12 have been rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

As noted above, original claims 1-14 have been replaced with new claims 15-21. The new claims are directed to a method of treatment by administering "anakinra". As described in the Specification at page 12, lines 4-14, anakinra is a recombinant, non-glycosalated form of the human interlukin 1 receptor antagonist which was *per se* known as of the filing date of the present application. Applicant submits that substitution of the original claims with new claims 15-21 renders moot the Examiner's written description rejection.

Reconsideration and withdrawal of the rejection are, therefore, requested.

4. Claim Rejection – 35 USC § 112 (Enablement)

Claims 1-14 have been rejected under 35 USC § 112, first paragraph, as allegedly lacking enablement in the Specification. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

First of all, it is noted that new claims 15-21 are drafted in the standard U.S. "method of treatment" format. Claims 1-7 drafted in the European style "second medical use" format have been canceled.

Applicants submit that much of the Examiner's alleged basis for the enablement rejection has also been rendered moot because the current claims are directed to administration of the product "anakinra".

Much of the Examiner's Office Action relates to a discussion of the "Wands factors" and a discussion of how those factors allegedly relate to non-enablement of Applicant's claims. But the Examiner's focus seems to be improperly based on whether the Applicant describes a specific working example or describes some actual clinical tests. First of all, it is not necessary for compliance with the enablement requirement for the Specification to contain either a working example or results of clinical tests. "The Specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation." MPEP § 2164.02, paragraph 3, citing, *In re Borkowski*, 164 USPQ 642, 645 (CCPA 1970). The present Specification describes prophetic examples at pages 21-28 and describes in-vitro test results at pages 28-37. Applicants submit that these descriptions, and others in the application, would fully enable one skilled in the art to make and use the claimed invention. In fact, the Examiner has not actually identified any allegedly missing teaching which one skilled in the art would need in order to make or use the present invention.

Accordingly, reconsideration and withdrawal of the rejection are requested.

It is noted that the Examiner has not rejected any of the claims over the prior art. It is, therefore, submitted that claims 15-21 obviate all of the Examiner's stated rejections, and the claims are in condition for allowance. Early action that effect is requested.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee of $120.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No.

30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: August 20, 2007

Respectfully submitted,

By

Leonard R. Svensson
Registration No.: 30,330
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive
Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicant